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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/706,325	11/03/2000	Juan M. Zapata	P-LJ 4453	6212

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EXAMINER

CANELLA, KAREN A

ART UNIT PAPER NUMBER

1643

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/706,325	ZAPATA ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75, 77, 79-83, 87-89 and 93-124 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 82, 88, 94, 97, 99-102, 110, 111, 114, 115, 118, 119, 122 and 123 is/are allowed.
- 6) ☐ Claim(s) 75, 77, 79-81, 83, 87, 89, 93, 95, 96, 98, 103-106, 108, 109, 112, 113, 117, 121, 124 is/are rejected.
- 7) ☐ Claim(s) 107 and 120 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 70-72 have been canceled. Claims 99-124 have been added. Claims 75, 77, 79-83, 87-89, 93-124 are pending and under consideration.

Sections of title 35, U.S. Code, not found in this action, can be found in a previous action.

The rejection of claims 75, 77, 80, 81, 83, 87, 89, 96 and 98 rejected under 35 U.S.C. 103(a) as being unpatentable over Comb et al (U.S. 6,441,140) in view of Brodeur et al (Journal of Biological Chemistry, 1997, Vol. 272, pp. 19777-19784) is maintained for reasons of record. New claims 103-106, 108, 109, 112, 113, 116, 117, 121 and 124 are also rejected for the same reasons of record.

Combs et al teach monoclonal and polyclonal antibodies which recognize degenerate motifs in a context-independent fashion (column 3, lines 44-50). Combs et al teach that said antibodies can be used to identify previously unknown substrates of a known enzyme by using the motif-specific context independent antibodies raised against motifs common to other substrates of said enzyme (column 4, lines 1-5). Combs et al do not specifically teach antibodies which bind to a context-independent motif on SEQ ID NO:12 or 25.

Brodeur et al teach the motif of PXQX(T/S) as a TRAF recognition site (page 19782, column 1, lines 2-6).

It would have been prima facie obvious at the time the invention was made to make monoclonal and polyclonal antibodies which specifically bind to the PXQX(T/S) motif by substituting the PXQX(T/S) motif for the alternative degenerate motifs taught by Combs et al,

such as the 14-3-3 motif (column 3, lines 53-57). One of skill in the art would have been motivated to do so by the teachings of Brodeur et al on the degenerate motif found in TRAF recognition sites. One of skill in the art would be motivated to find other proteins which also comprised said TRAF recognitions sites. The resulting antibodies would bind the instant SEQ ID NO:12 and 25 which have the PXQX(T/S) motif at residues 33-37 and 30-34, respectively.

Further, it would be inherent in the properties of the antibodies which bind to the motif that said antibody would inhibit the association between the TPBD and TRAF or a TRAF-associated protein

Applicant argues against the teachings of Brodeur et al stating that constructs expressing fragments comprising the motif failed to bind to any of TRAF2, TRAF3, TRAF5 or TRAF6. This has been considered but not found persuasive. Brodeur et al teach that TRAF3 binds to critical residues localized between amino acid 196 and 212 including the PXQX(T/S) motif and that mutation of critical residues in the TRAF3 binding site of LMP-1 will prevent the binding of TRAF2, TRAF3 and TRAF5 (abstract). Thus, applicants arguments about the Brodeurs teachings about the recognition motif for TRAF are moot.

The rejection of claims 75, 79, 81 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al (FEBS Letters, 1997, Vol. 418, pp. 23-26, cited in a previous action) in view of Campbell (Monoclonal Antibody Technology, 1985, pages 1-32) is maintained for reasons of record.

Nagai et al teach an amino acid sequence, SPOP, consisting of all of residues 1-132 of SEQ ID NO:24. Nagai et al produce the recombinant antibody using a "HA" tag and detect said

tagged protein by means of an anti-HA antibody. Nagari et al do not teach an antibody which binds to the SPOP protein without the HA tag.

Campbell teaches that the potential of monoclonal antibodies in the basic research is considerable because they can resolve a single protein from a complex mixture or indeed a single epitope responsible for a specific function of a complex macromolecule. Campbell also teaches that it is customary now for any group working on a macromolecule to both clone the genes coding for it and make monoclonal antibodies to it (sometimes without a clear objective for their application)" (page 29, section "Basic research" in particular).

It would have been prima facie obvious at the time the invention was made to make a monoclonal antibody to SPOP. One of skill in the art would have been motivated to do so by the teachings of Campbell et al and because it would enable one of skill in the art to detect the natural protein without need for the HA tag.

The rejections of Claims 75, 79, 81, 83 and 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al (FEBS Letters, 1997, Vol. 418, pp. 23-26) and Campbell (Monoclonal Antibody Technology, 1985, pages 1-32) as applied to claims 75, 79, 81 and 93 above, and further in view of Paul (Fundamental Immunology, 1993, text, pages 460-461) is maintained for reasons of record.

Claim 83 embodies the antibody of claim 75 wherein said antibody is a polyclonal antibody. The combination of Nagari et al and Campbell render obvious the instant claims with respect to a monoclonal antibody. The combination does not teach a polyclonal antibody.

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Paul teaches that advantages of polyclonal antibodies over monoclonal antibodies in certain situations where multi-valency is important (page 460, second column, third paragraph under the heading "Polyclonal Versus Monoclonal Antibodies").

It would have been prima facie obvious at the time the claimed invention was made to make a polyclonal antibody which would directly bind to the SPOP protein of Nagai et al. One of skill in the art would have been motivated to do so by the teachings of Paul on the advantages of polyclonal antibodies, and because one of skill in the art would want to be able to detect the SPOP protein in the natural state without requiring the HA tag.

Applicant argues that Nagi et al does not anticipate the claimed sequence because the protein of Ngai et al is 374 amino acids in length and the instant protein is 132 amino acids in length. This has been considered but not found persuasive. There is no language in any of the claims that would limit the TPBD to an amino acid sequence consisting of SEQ ID NO:24. It is noted that the language of the MARKUSH group in claims 75 and 103 does not serve as closed language with respect to the identity of the amino acid sequence, but serves as closed language with respect to elements of the group. For instance, selected from the group consisting of SEQ ID NO:12, 24 and 25 means that the group consists of the three sequences of SEQ ID NO:12, 24, and 25. However, without specific language stating that the individual sequences consist of SEQ ID NO:12, 24 or 25, the broadest reasonable interpretation includes amino acid sequences comprising SEQ ID NO:12, 24 or 25.

Claims 107 and 120 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base

claim and any intervening claims.

All other rejections and objections as set forth or maintained in a previous Office action are withdrawn.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
4/28/2006


KARENA. CANELLA PH.D
PRIMARY EXAMINER